DEPARTMENT OF HEALTH & HUMAN SERVICES

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2002-DT-16

December 14, 2001

Mr. James A. Van Haitsma, Owner
Van Haitsma Dairy Farm
6785 Mulder Rd.
Falmouth, MI 49632

Dear Mr. Van Haitsma:

An investigation at your dairy farm conducted by Investigator Kelley L. Clark on October 19, 2001 confirmed that you offered animals for sale for slaughter as food in violation of sections 402 (a) (2) (C) (ii) and 402 (a) (4) of the Federal Food, Drug, and Cosmetic Act.

On or about August 2, 2000, you sold a dairy cow identified as cow #774 from your farm through [redacted] to [redacted] for slaughter as human food. This cow was slaughtered on August 7, 2000 and USDA analysis of tissue samples collected from that animal identified the presence of gentamicin residue [redacted] parts per million (ppm) in the kidney). A tolerance level of 0 ppm in the kidney has been established for residues of gentamicin in the edible tissues of dairy cows. The presence of this drug in the edible tissue from this animal causes the food to be adulterated.

In addition, the USDA reported the finding of illegal residues in another dairy cow identified as originating from your farm. This animal was identified by back-tag #345 and was sold and shipped to [redacted] where it was slaughtered on January 18, 2000 as human food. USDA analysis of tissue samples collected from that same animal identified the presence of penicillin residue ([redacted] ppm in the liver) and gentamicin residue [redacted] ppm in the liver and [redacted] ppm in the kidney). A tolerance level of 00.05 ppm has been established for residues of penicillin in the edible tissues of dairy cows. As previously mentioned, a tolerance level of 0 ppm has been established for residues of gentamicin in the edible tissues of dairy cows. The presence of these drugs in the edible tissues from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially harmful drug residues are likely to enter the food supply. Our investigation found that you lack

an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species, for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated by you have been withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such control is adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce, is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to David M. Kaszubski, Director Compliance Branch, U.S. Food and Drug Administration, 1560 E. Jefferson, Detroit, MI 48207, telephone (313) 226-6260 ext. 185.

Sincerely,

for David M. Kaszubski
Joann M. Givens
District Director
Detroit District